MAR 2 0 2001

K010560

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, Indiana 46581

Proprietary Name: Portrait™ Femoral Component

Common or Usual Name: femoral component

Classification Name: prosthesis, hip, semi-constrained, metal/polymer, uncemented

Device Classification: Class II

Device Product Code: LWJ

Device Description: The Portrait™ Femoral Component is a modification to the Lester Femoral Component cleared under 510(k) number K915500.

The Portrait™ Femoral Component is a flat, tapered stem proportionally designed to match the geometry of the femur. This design provides rotational stability by wedging itself into the femoral canal. The collarless design also ensures proper seating so that intimate contact between the prosthesis and bone is achieved. The taper of the femoral stem parallels the shape of the femoral canal, allowing a gradual decrease in the stresses transferred to the bone from proximal to distal and achieve exceptional femoral fit.

The stems are proportionally sized and shaped in twelve sizes (sizes 1-12). The distal tip of the prosthesis is designed in a pyramidal shape and rounded for better load transfer and stress shielding prevention in the distal femur. The Portrait™ Femoral Component is manufactured from Ti-6Al-7Nb per ASTM 1295.

Indications for Use: 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The Portrait Femoral Component is intended to be use without bone cement.

Potential Risks:

1. Major surgical risks associated with anesthetic including: brain damage, pneumonia, blood clots, heart attack, and death.
2. Cardiovascular disorders including venous thrombosism pulmonary embolism, and mycardial infarction.
3. A sudden drop in blood pressure intraoperatively due to the use of bone cement.
4. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
5. Temporary or permanent nerve damage may result in pain and numbness.
6. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene component of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
7. Early or late postoperative, infection, and allergic reaction.
8. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock cause by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
9. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resportion, excessive activity.
10. Perarticular calcification or osseification, with or without impediment or joint mobility.
11. Inadequate range of motion due to improper selection or positioning of components.
12. Undesirable shortening of limb.
13. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
14. Fatigue fracture of component may occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
15. Fretting and crevice corrosion may occur at interfaces between components.
16. Wear and/or deformation of articulating surfaces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2001

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K010560
Trade Name: Portrait™ Femoral Component
Regulatory Class: II
Product Code: LZO and LWJ
Regulation: 21 CFR 888.3353
Dated: February 7, 2001
Received: February 26, 2001

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K010560

Device Name: Portrait™ Femoral Component

Indications for Use:
The Portrait™ Femoral Component is indicated for use in patients requiring total hip replacement due to the following:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

The Portrait Femoral Component is intended to be use without bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IS NEEDED)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010560